UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
GENERAL INFORMATION

The University of Cincinnati maintains Institutional Review Boards (IRBs) for human subject research performed by researchers of all levels at the University. The IRB - Medical (IRB-M) primarily reviews studies with a biomedical focus and the IRB – Social and Behavioral Sciences (IRB-S) primarily reviews behavioral/psychosocial studies.

The basic function of an IRB is to protect the rights of research participants. This is accomplished by reviewing research proposals to ascertain that the participants:

- are not exposed to undue risks by the research.
- have been informed of the nature and procedures of the research, and
- participate voluntarily as evidenced by the subject's consent.

Based on provisions of the Department of Health and Human Services Regulations for Protection of Human Subjects found in Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46) (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm) and in order to comply with the University's Federal Wide Assurance, the IRBs were established to review research projects conducted by anyone on the premises of the University as well as research conducted off campus by University faculty, students, staff or other UC representatives and research using non-public information collected by the University.

Following the federal guidelines, "research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Before initiating any such research project (contacting prospective human participants, collecting pilot data, etc.), the principal investigator (PI) must first submit a research protocol for review by the IRB. Forms and guidelines can be printed from the IRB website (www.med.uc.edu/irb, click IRB Forms, click the desired form, and print).

Information about IRB-M policies and procedures may be obtained from the IRB website or from the IRB-M Administrator, Carolyn West (phone: 558-7348, fax: 558-4111, email: Carolyn.West@uc.edu). Information about IRB-S policies and procedures may be obtained from the IRB-S Program Manager, Claudia Norman (phone 513-558-5784 or Claudia.Norman@uc.edu. Or, information about IRB policies and procedures may be obtained from the Director of Institutional Research and Compliance Services, Mary Belskis (phone: 558-5105, fax: 558-4111, email: Mary.Belskis@uc.edu).

SUBMISSION TO THE IRB-SOCIAL AND BEHAVIORAL SCIENCES

NEW RESEARCH PROPOSALS

In certain circumstances a "pending" IRB-S number can be issued before the protocol is submitted to the IRB-S for review. RECEIPT OF A "PENDING" IRB-S NUMBER DOES NOT MEAN THE PROTOCOL IS APPROVED. All protocol documentation must still be submitted for review according to the guidelines mentioned below. When the IRB-S has approved a protocol, clearly identified documentation of approval will be provided.

A "pending" IRB-S number is valid for one year. If no protocol has been submitted within a year the number will be cancelled.

A protocol may be submitted at any time. Research that is determined to meet the criteria for Exempt status or Expedited review is not subject to deadlines. Research that is determined to require review by

the full IRB-S is subject to submission deadlines. These may be found on the IRB-S Meeting Schedule (see attached list).

Generally, the process is as follows:

- The researcher submits the proposal according to the attached format guidelines.
- The Chair of the IRB-S decides, based on federal regulations, if the research is Exempt from further IRB-S oversight, qualifies for Expedited review, or must undergo review by the Full IRB-S.
- If Exempt, the researcher is sent a letter immediately indicating that he/she may proceed with the project.
- If Expedited, the proposal is sent to a selected number of IRB-S members for review. They can approve it, request changes or disapprove it. The researcher will be contacted and either given approval or asked to submit changes/additions prior to approval. If it is disapproved at this point, it goes to Full Board review.
- If Full Board review, it is discussed at a convened IRB-S meeting. The researcher should be available to address the Board if questions arise during the discussion. The IRB-S can approve, request changes or disapprove the study.

The IRB-S must make the final determination of the review type. Therefore, even if the PI believes that his/her project should be exempt, sufficient details of the research plan must be provided (i.e., description of prospective participant population, nature of participant recruitment, research methods and procedure) to permit a judgment to be made by the IRB-S.

In most cases, review takes 21-28 working days. The total time is dependent on the extent of the revisions and the PI's response time to revision requests.

Whatever the review type, THE IRB-S WILL ADMINISTRATIVELY CLOSE A PROTOCOL IF THE RESEARCHER HAS NOT RESPONDED TO REVIEWERS' COMMENTS WITHIN A YEAR.

CONTINUING APPROVAL OF RESEARCH

IRB-S approval of a project involving human subjects extends for not more than one year. The exact interval of approval and date of expiration are provided in the approval notification letter. Prior to the anniversary date of approval, a Progress Report form must be submitted by the PI giving information about the status of the project. A Progress Report form may be printed from the IRB website. Federal regulations require that IRB-S review be carried out before a previously approved project can continue into another year. IF A PROGRESS REPORT HAS NOT BEEN APPROVED BY THE IRB-S BEFORE THE APPROVAL EXPIRATION DATE, FEDERAL REGULATIONS REQUIRE TERMINATION OF THE PROTOCOL.

COMPLIANCE WITH IRB-S REQUIREMENTS

Failure to comply with IRB-S requirements constitutes a breach of federal regulations. All researchers who work with human subjects must understand that any failure to be in compliance with these regulations could threaten both federal funding of research within the University of Cincinnati and the continuation of other research. Other major universities have had entire research programs shut down for failure to follow regulations, and faculty and students can receive administrative sanctions. Most importantly, however, compliance reflects respect for protection of individuals and of their right to make informed decisions about what is happening to them.

- IRB-S Packet (Adobe PDF format)
- IRB-S Meeting Schedule (Adobe PDF format)
- Ethical Principles and Guidelines for Research Involving Human Subjects (Adobe PDF format)

Contacts

For basic information concerning forms, guidelines, etc., please contact the IRB-S Program Manager, Claudia Norman (phone: 513-558-5784, fax: 55-4111, e-mail: Claudia.Norman@uc.edu). Inquiries concerning the IRB-S review process may be directed to the IRB-S Chairperson, Margaret Miller, Ed.D. (phone: 558-5212, e-mail: Margaret.Miller@uc.edu) or to the Director of Institutional Research and Compliance Services, Mary Belskis (phone: 558-5105, Fax: 558-4111, email: Mary.Belskis@uc.edu).

Last update 10/03

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
RESEARCH REVIEW SUBMISSION FORM

1. PRINCIPAL INVESTIGATOR INFORMATION:
   - A Social Security Number (SSN) must be provided for each person to ensure accurate entry for compliance tracking. If the person HAS an appointment at UC, ONLY THE LAST 4 DIGITS ARE NEEDED. If the person does NOT have an appointment at UC, the entire SSN is needed. All SSN's will be removed before this form is distributed to the IRB reviewers.
   - A Conflict of Interest form (Appendix A) must be provided for each person listed below.
   - Graduate and Undergraduate STUDENTS conducting research to meet requirements of a UC academic program MUST HAVE A FACULTY ADVISOR LISTED as the Co-Principal Investigator (Co-PI). Correspondence will be sent both to the student and to the faculty advisor.

Principal Investigator
Name & Degree Bettie C. Hall, M.Ed.
Rank/Title Graduate Student SSN
College Education, Criminal Justice, and Human Service Dept Teacher Education, Curr. & Inst.
Room & Building 613 Teachers College Mail Location # 0002
E-mail hallbe@email.uc.edu Phone # 513-706-5695 Fax # 513-556-1001
Home address (if student) 9256 Village Green Drive, Cincinnati, OH 45242

Co-Principal Investigator
Name & Degree Joyce Pittman, Ph.D.
Rank/Title Assistant Professor SSN
College CECH Dept Teacher Education
Room & Building 608D Teachers Mail Location # 0002
E-mail joyce.pittman@uc.edu Phone # (513) 556-4385 Fax # (513) 556-1001
Home address (if student)

2. PROJECT TITLE (refer to this title in all correspondence)
Accommodating Adult Learning Styles using Educational Technologies

3. DURATION OF THE STUDY
Date of expected start of the study November, 2005
Date of expected completion of the study June, 2006

4. LOCATION (where research study will be conducted)
Name of site College of Engineering
Address 551 Baldwin
Second site College of Education
Address 613 Teachers College

5. INFORMED CONSENT

a. Is a signed consent being used? ☑ Yes ☐ No
If no, please provide rationale [go to www.med.uc.edu/irb, click IRB Forms, click Informed Consent Guidelines and see 45CFR46.116(d)]. _____

b. What is the reading grade level of the informed consent document? 12.0
In Microsoft Word, click Tools, click Options, click Spelling & Grammar tab, click Grammar with spelling check box, click Show readability statistics check box, click OK. Then spell-check the consent document and readability statistics will show.

c. For those studies that involve information that needs to be protected from subpoena, will a Certificate of Confidentiality be requested from NIH? ☐ Yes ☑ No (for information on Certificates of Confidentiality see http://grants1.nih.gov/grants/policy/coc/index.htm)
If yes:
1) does the consent form advise the participant of situations where the PI may voluntarily comply with state laws, such as the reporting of child abuse, elder abuse, or immediate danger to self or others? ☐ Yes ☐ No
2) has the confidentiality statement been modified to be consistent with the Certificate of Confidentiality protections? ☐ Yes ☐ No

d. Describe and justify any anticipated costs to the study participants None

6. EXTERNAL FUNDING INFORMATION

Funding Source This is a pilot study for a future funding opportunity.
(Note: if a federally funded study, one copy of the grant application must be included)

7. STUDY SPECIFIC INFORMATION

a. Expected number of participants 30

b. Age range of participants 18-60

c. Will this study enroll any participants from the following categories?
(Check all that apply. Note: research involving any treatment of patients must be reviewed by the medical IRB): The PI must obtain the attending physician's approval before approaching any hospitalized patient for participation in a study: ☐ Patients
☐ Under 18 years old ☐ Cognitively impaired ☐ Prisoners ☐ Pregnant women
☐ Others vulnerable to coercion (e.g., students of the teacher/PI, employees, etc.)
_____

d. For research involving participants less than 18 years of age, please indicate which of the following categories most accurately describe this protocol (45CFR46, Subpart D):

- ☐ minimal risk
- ☐ greater than minimal risk (46.404)
- ☐ greater than minimal risk but of direct benefit to individual (46.405)
- ☐ greater than minimal risk with no direct benefit to individual, but likely to yield generalizable knowledge (46.406)
- ☐ research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of minors (46.407)

8. RECRUITMENT

How will participants be recruited for this study? (check all that apply)

☐ Referrals ☐ Letter ☐ Brochure ☐ Poster ☐ Newspaper/Radio/TV ad
☐ Dept. Subject Pool ☑ Academic course ☐ Sign-up sheet ☐ Internet ☐ Web site
☐ Other (explain) _____

(A sample of all recruitment materials including radio script, videotape, etc., must be provided.)

9. ETHICAL ISSUES

a. Does the study involve: (check all that apply) ☑ None of these

☐ Painful or aversive stimuli ☐ Emotional stress ☐ Deception ☐ False information
☐ False feedback ☐ Withholding of critical information

Please explain all those that have been checked and address the question of potential psychological harm to participants. _____

---

b. What residual effects of the procedures have been explored? No adverse residual effects are anticipated

c. How will the project be monitored so that any unexpected or adverse events that pose a risk to participants are promptly brought to the attention of the principal investigator? Not applicable are anticipated

d. What safeguards have been taken to insure protection against risks for any participant who is especially sensitive or vulnerable? No known risks

e. If the study involves deception, false information, false feedback, or withholding of critical information, will the participant be told why or debriefed? ☐ Yes ☐ No
Please explain. Not applicable

f. Are participants aware that data are being recorded or that they are under observation?
☑ Yes ☐ No
If no, please explain. _____

g. Will any other data of a personal nature be gathered about the participant from other sources? ☐ Yes ☑ No
If yes, please explain. _____

h. If the answer to item 9g is yes, will the participant be asked to consent to this collection of personal data from other sources? ☐ Yes ☐ No
If no, please explain. N/A

i. Are there any aspects of the study which might constitute an invasion of the participant's privacy for which consent has not expressly and implicitly been given? ☐ Yes ☑ No
If yes, please explain. _____

j. Participants must be able to withdraw at any time without difficulty, undue embarrassment, or negative consequences. How are participants made aware of their right to withdraw from the study? Participants are informed of their right to withdraw from the study on the Participant Consent Form.

k. Are all personnel involved in carrying out the research familiar with the ethical guidelines for research involving human participants? ☑ Yes ☐ No
If no, how will this deficiency be corrected? _____

(Such guidelines can be found in American Psychological Association. (1982). Ethical Principles in the Conduct of Research with Human Participants. Washington, DC, American Psychological Association, or American Psychological Association. (1992). Ethical Principles of Psychologists and Code of Conduct. Washington, DC, American Psychological Association.)

10. KEY PERSONNEL

- List co-investigators or other key individuals who will have contact with the participants in the study. A Social Security Number (SSN) must be provided for each person for compliance tracking. If the person HAS an appointment at UC, only the last 4 digits are needed. If the person does NOT have an appointment at UC, the entire SSN is needed. All SSN' s will be removed before this form is distributed to the IRB reviewers.
- A Conflict of Interest form (Appendix A) must be provided for each person listed. Use an additional page if necessary.

Name & Degree Bettie C. Hall, M.Ed. SSN 6871
Responsibility in Project Principal Investigator
Department/Address Teacher Education, Curr. & Inst.,

Name & Degree Dr. Joyce Pittman SSN _____
Responsibility in Project Co-PI
Department/Address 613 Teachers College, P.O. Box 210002, Cincinnati, OH 45221-0002

11. RESEARCH CONDUCTED BY STUDENTS

a. If the principal investigator is a student, the following information must be provided.

Check one: ☑ Doctoral student ☐ Master's student ☐ Undergraduate student

b. Describe the nature and extent of faculty sponsorship or supervision on this project.

Dr. Joyce Pittman will supervise this pilot study. This is expected to extend

c. If this research project is being conducted as part of a master's thesis or doctoral dissertation, please list the committee members:

Chair Dr. Joyce Pittman and Dr. Ken Martin, Co-Chairs

Dr. Glenn Markle

Dr. Janet Bohren

Dr. Rebecca Scheckler

12. SIGNATURES and CERTIFICATION

a. The PI agrees to accept responsibility for the scientific conduct of the project, and certifies that the scientific portion of the protocol is original and contains no false, fictitious, or fraudulent statements or data.

b. The PI certifies that the Conflict of Interest disclosure statements enclosed are up-to-date for all key personnel for this project.

c. The Faculty Advisor certifies that the student PI has the proper education, experience, and expertise to conduct the study.

Principal Investigator (legible signature)	Date	Faculty Advisor (if PI is a student) (legible signature)	Date

APPENDIX A

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
CONFLICT OF INTEREST DISCLOSURE

A Conflict of Interest statement is required for EACH individual listed in # 1 and #10 of the Research Review Submission Form.

Principal Investigator's Name(s) (print): Bettie C. Hall
Study Title Accommodating Adult Learning Styles using Educational Technologies
Person Completing this Form (print) Bettie C. Hall

Except for grant-funded compensation and expenses, do you, or does any member of your immediate family, intend or expect to profit financially in any manner from the results of the research undertaken in this study (including, but not limited to any patent, royalty, or licensing fees)? ☑ Yes ☐ No

If yes, please provide a detailed description of your financial intentions or expectations:
This is a pilot for a planned dissertation study that may last more than one year. The PI intends to apply to funding from various agencies, including the Dept. of Education and the National Science Foundation.

Do you, or does any member of your immediate family, currently have or expect to have an ownership or other financial interest in, or management position with any entity whose procedure, technique, product or software is used or tested in this study? ☑ Yes ☐ No

If yes, please provide a detailed description of your financial interest or management position:
The PI holds a copyright to the textbook material that will be used as a basis for the instructional strategies to be developed as part of this study.

Legible Signature Date

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
PROTOCOL FORMAT CHECKLIST (page 1 of 3)

PI / IRB# _____ Reviewer _____

To ensure a prompt and thorough evaluation, the following information must be submitted to the IRB-S. Please compare your protocol to this checklist. IF ANY ITEMS ARE MISSING, GIVE EXPLANATION IN "COMMENTS" LINE.

OK	MISSING		COMMENTS
___	___	1. **PROTOCOL** including the following elements IN THIS ORDER:	_____
___	___	a. Purpose or aim of the study	_____
___	___	b. Research objectives	_____
___	___	c. Significance of the study.	_____
___	___	d. Brief summary of the background to the present research, including previous and/or preliminary relevant studies	_____
		e. Detailed description of the procedures to be used, including:	
___	___	1) Participants' age	_____
___	___	2) Participants' sex	_____
___	___	3) Approximate number of participants	_____
___	___	4) Criteria used to decide who is eligible to participate	_____
___	___	5) Source of participants (e.g., UC campus, Clifton Elementary math classes, etc.)	_____
___	___	6) Description of how participants will be recruited,	_____
___	___	(including plans for institutional/agency approval where participants are recruited and data are collected, if appropriate).	_____
___	___	7) Recruitment incentives, if any (lottery incentives are NOT allowed)	_____
___	___	8) Setting for the study (i.e., classroom, internet, etc.)	_____
___	___	9) Detailed description of the interventions, activities,	_____
___	___	or experimental aspects of the study (this should be consistent with procedures explained in the consent)	_____
___	___	10) Alternative interventions, activities or procedures which participants may choose, if any	_____
___	___	11) Description of how informed consent will be obtained	_____
___	___	12) Description of how anonymity or confidentiality will be preserved	_____
___	___	(a) If identifiers are retained, explain why this is necessary	_____
___	___	(b) and how long the identifiers will be kept.	_____
___	___	(c) If audio/video recordings are made, explain what will become of these tapes	_____
___	___	13) Description of how research staff will be trained and monitored to obtain consent, interact with participants, collect data, analyze data, and follow the basic guidelines for the ethical treatment of participants	_____
___	___	14) If applicable, explanation of discrepancies between the submitted protocol and the grant, and the reason for discrepancies	_____
___	___	f. Brief description of evaluation/data analysis procedures used to determine study findings	_____
___	___	g. Detailed description of any potential risks or discomforts participants may experience in the study	_____

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
FORMAT CHECKLIST FOR NEW PROPOSALS (page 2 of 3)

OK	MISSING			COMMENTS
___	___	h.	Explanation of how problems or discomforts will be handled if they occur	_____
___	___	i.	Description of potential benefits of this research to the individual participant, if any. (Payment as a recruitment incentive is not considered a benefit of research.)	_____
___	___	j.	If no direct benefit to the participant is expected, this should be clearly stated	_____
___	___	**2.**	Attach samples of all **RECRUITMENT MATERIALS** (i.e., letter, brochure, poster, newspaper advertisement, Internet, web site, etc.) after the protocol	_____
___	___	**3.**	Attach **CONSENT DOCUMENT(S)** after the protocol	_____
___	___	a.	Adult consent (for participants 18 years or older)	_____
___	___	b.	Parental permission (for participants under 18 years old)	_____
___	___	c.	Child assent (for participants 8 to 17 years old)	_____
			See "Informed Consent Instructions" for guidance in preparing a consent document.	
___	___	d.	NOTE: Anonymous surveys may avoid the need for a consent document by stating at the beginning of the survey: "By completing this survey I indicate my consent to participate in this study." For further instructions about preparing an informed consent document, go to www.med.uc.edu/irb, click IRB Forms, click Informed Consent Instructions.	_____
___	___	**4.**	Attach samples of all **DATA COLLECTION INSTRUMENTS** (i.e., questionnaires, focus group/interview guides, observation guides, test instruments, study equipment, etc. used to collect data) after the protocol	_____

ASSEMBLE THE RESEARCH PROPOSAL MATERIALS IN THIS ORDER:

Research Review Submission Form (RRSF)
- Faculty Advisor MUST be a Co-Principal Investigator both for graduate and undergraduate student PIs.
- BOTH student PI and Faculty Advisor must sign item 12.
- BOTH student PI and Faculty Advisor must provide a Conflict of Interest form (Appendix A).

Protocol
- This checklist should be the FIRST item of the protocol.
- A cover letter is not required. If one is provided, put it AFTER this checklist.
- The items listed in this checklist must be included in the protocol IN THE ORDER SHOWN.
- Data collection materials
- Recruitment materials
- Informed consent document(s)

Federal grant application (if applicable)

Send 5 copies of RRSF and Protocol (including all attachments)
and one copy of the federal grant, if applicable, to:

ATTN: Claudia Norman
U.C. IRB-S, M.L. 0567
Wherry Hall, Rm. G-08
P.O. Box 670567
Cincinnati, OH 45267-0567

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
FORMAT CHECKLIST FOR NEW PROPOSALS (page 3 of 3)

The IRB will do everything possible to help investigators meet any time constraints such as course or degree deadlines. However, as defined in federal regulations, the purpose of the IRB is to protect human subjects.

IT IS THE INVESTIGATOR'S RESPONSIBILITY TO PROVIDE ALL NEEDED INFORMATION TO THE IRB WITH SUFFICIENT TIME TO ALLOW ADEQUATE IRB REVIEW AND ANY REVISIONS which may be necessary before approval can be granted. The time needed for review depends greatly upon the type of study, the clarity of submitted materials and how quickly the investigator is able to respond to reviewers' comments.

NO RESEARCH PARTICIPANTS MAY BE RECRUITED NOR DATA COLLECTED WITHOUT AN APPROVED PROTOCOL, THUS THE INVESTIGATOR MUST ALLOW SUFFICIENT TIME FOR THE PROTOCOL TO BE REVIEWED AND APPROVED. Failure to comply is a breach of federal regulations and threatens all federal funding of research within the University of Cincinnati including continuation of established research.

If you have any questions regarding these procedures, please contact Claudia Norman, IRB-S Program Manager, at 513-558-5784 or Claudia.Norman@uc.edu.

10/03

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
INFORMED CONSENT INSTRUCTIONS

The Informed Consent Statement is designed to protect the rights and well-being of the participant.

- Clear explanations of all of the following "basic elements" are required.
- "Additional elements" should be included as appropriate to the study.
- The format and wording may be adapted to the nature of the research and the comprehension level of participants.
- THE READING GRADE LEVEL OF THE CONSENT DOCUMENT SHOULD BE CITED IN THE RESEARCH REVIEW SUBMISSION FORM ITEM 5(b). In Microsoft Word, click Tools, click Options, click Spelling & Grammar tab, click Grammar with spelling check box, click Show readability statistics check box, click OK. Then select (highlight) the body of the consent and run the spell-check feature. The readability statistics will show. The consent title block and signature lines do not have to be included in readability statistics.

A sample Informed Consent Statement has been provided at the end of the federal regulations below.

Format details to be observed:

- The participant should be addressed as "you" and the investigator(s) as "I/we."
- Vocabulary and document layout should be at a level appropriate for the participant's comprehension. Font size, paragraph breaks and/or bullets may need adjustment to enhance readability. It is best to keep the information in the order shown in the sample consent below.
- Only section headings may be in bold type. For emphasis, use ALL CAPITALS, <u>underline</u> or *italics*.
- The document must not contain any exculpatory language through which the participant waives or appears to waive any legal rights.
- Provide appropriate signature lines (participant and person explaining the consent are required, parent/legal guardian and/or witness only when needed).
- Proofread document for typos and grammatical errors.
- Refer to "Consent Form Checklist Used by Reviewers" to see the kinds of items being examined by the reviewers. Failure to include necessary elements will delay approval of the study.
- Questionnaire studies which qualify for waiver of signed consent must include the following statement at the beginning of the questionnaire: By completing this questionnaire, I indicate my consent to participate in the study.

Below are the federal regulations that specify those items that must be included in all consents and those items that should be provided when appropriate. The federal regulations for written documentation, alteration and waiver of consent are also included.

<u>MINORS AS PARTICIPANTS</u>

When minors (individuals less than 18 years of age) are involved in research, the regulations require the ASSENT of the minor and the PERMISSION of the parent(s), in place of the CONSENT of the participants. The IRB-S must take into consideration the soliciting of assent of the minors when in the judgment of the IRB-S the minors are capable of providing assent (45CFR46.408). The federal regulations do not require that assent be sought from minors starting at a specific age, however, the IRB shall take into account the ages, maturity, and psychological state of the minors involved. The provisions for obtaining and documenting assent must be adequate and clearly described.

The UC IRB-S usually expects only parental permission for participants younger than 8 years old, but parental permission AND child/adolescent assent for participants 8 years to 17 years old. In most cases the permission and assent forms should be separate documents, and often require different reading levels.

PARTICIPANTS WHO DO NOT SPEAK ENGLISH

Participants who do not speak English should be presented with an informed consent document written in a language they do understand. This procedure is strongly recommended whenever possible. The regulations allow for oral presentation of informed consent information in conjunction with a short form written informed consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the participant must be given copies of the short form document and the summary. When this procedure is used with participants who do not speak English, (i) the oral presentation and the short form written informed consent document should be in a language understandable to the participant, (ii) the IRB approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the participant.

The UC IRB-S has determined that research conducted in a foreign country where English is not the primary language does not require English to be used in the consent process. However, an English translation of the consent must be provided to the IRB. In addition, a person fluent in the foreign language must provide written confirmation that the non-English and the English consents are equivalent.

GENERAL REQUIREMENTS FOR INFORMED CONSENT - 45CFR46.116

(a) **BASIC ELEMENTS OF INFORMED CONSENT**. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

(b) **ADDITIONAL ELEMENTS OF INFORMED CONSENT**. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted or subject to approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

DOCUMENTATION OF INFORMED CONSENT – 45CFR46.117

(a) except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required in §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
SAMPLE INFORMED CONSENT STATEMENT

The following sample informed consent document includes instructions to the person writing the document followed by sample language that may be used in the actual document. {Instructions to the person preparing the document are always written in script and enclosed in brackets, like this.} Sample language that may be used in the actual document is always written in standard typeface, like this.

{The title block below must appear in **bold print** at the top of all informed consent documents. Section headings should be in **bold print**. The text of the informed consent document should be in regular print.}
Link to Informed Consent Checklist

University of Cincinnati
Consent to Participate in a Research Study
College/Departmental affiliation
Investigator's name
Investigator's telephone number/email

Title of Study:
{In some cases the validity of the study may be compromised by informing participants of the hypothesis. The protocol/consent title may require careful wording. Occasionally the consent title may need to be different from the protocol title but the rationale for the variance MUST be CLEARLY explained in the protocol.}

Introduction:
{This statement may be paraphrased, depending on the participants' reading and comprehension level, but some statement of this type must be included.}

Before agreeing to participate in this study, it is important that the following explanation of the proposed procedures be read and understood. It describes the purpose, procedures, risks, and benefits of the study. It also describes the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made as to the results of the study.

Purpose:
{Provide a statement describing the purpose(s) of the study, and an indication of how many persons are participating in the study (hereafter known as "participants").}

The purpose of this research study is _____

You will be one of approximately (number) participants taking part in this study.

Duration:
{Provide a statement describing the expected duration of the participants' involvement in the study (for example, "30 minutes" or "one hour each week for six weeks", etc.).}

Your participation in this study will last for approximately _____.

Procedures:
{Provide a description of the procedures of the study. If there are any procedures that are experimental, these must be identified. Explain in clear, layman's language, step by step, what will happen to the participant. This should include, but not be limited to:

- Procedures to be performed, including number, frequency, and duration, such as interviews, observations, etc.
- Differentiate between procedures that are for research and those that are standard, i.e., teaching methods, assignments, etc.
- Any other data to be collected, such as written material, teacher comments, etc.
- Specify any post study follow-up, such as debriefing session}

During the course of this study, the following will occur:

Exclusion:
{Only include this section if applicable. Clearly list criteria that would prevent an individual from participating or make someone ineligible to participate.}

You will not be able to participate in this study if any of the following apply to you:

Risks/Discomforts:
{For each foreseeable procedure/intervention, which is a part of the research, describe the immediate and long-term discomforts/hazards/risks (physical/psychological/educational) and their consequences. If the incidence of these discomforts or risks is known from previous studies, it also should be stated. Explain safeguards and/or precautions that will be taken to reduce the occurrence of adverse effects. Explain what treatment or assistance will be available should any of the stated adverse effects occur.}

The study may involve the following discomforts and/or risks:

The safeguards or precautions to avoid these discomforts or risks are:

There also may be discomforts and risks that are not yet known.

Marketable Material:
{Only include this section if applicable.}

There is a possibility that this research may result in the development of a commercially valuable product or procedure. The investigator and the institution may benefit from the sale of such product or procedure.

Benefits:
{Only include one of the following choices. This statement should describe reasonable benefits to the participant as a result of participation in the research. Identify those to be gained by the individual participant, as well as those by society in general. If the individual participant will receive NO DIRECT BENEFIT, this must be explicitly stated. Payment for participation is not considered a benefit of the research.}

The benefits to you for participating in this study may be _____. However, you may receive no benefit from participating in this study.

OR

You will receive no direct benefit from your participation in this study, but your participation may help (teachers, retailers, health care practitioners, etc) better understand _____.

Alternatives:
{Provide a statement describing appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant (i.e., participate in the class but data will not be entered into the study). Some of these may be educational interventions in the classroom, or behavioral or social interventions, etc. Identify any risks of the alternative procedure, if any. If the only alternative is simply to not participate in the study this should be stated.}

The following alternative procedure or intervention is available to you if you choose not to participate in this study _____.

New Findings:
{Only include this statement if your study involves on-going participation such as repeated interviews. Do not include this statement if your study only involves one episode of participation such as a single questionnaire.}

You will be told if there is any new information that becomes available during the course of the study that may affect your willingness to continue participation in the study.

Confidentiality:
{This section should describe the extent to which confidentiality of records identifying the participant will be maintained, i.e., coding of research data, storage of identifiable data in locked files, who has access to data, limitations to confidentiality, etc. Confidentiality procedures explained here must be consistent with confidentiality procedures stated in the research protocol. Be sure to explain disposition of data at the conclusion of the study. Language provided below is ONLY an example.}

Your research data will be kept in a locked file cabinet in the investigator's office. Only the investigator will have access to your data. After audiotapes of the interview have been transcribed the audiotapes will be erased. Research data will be stored in a locked file cabinet for three years after the end of this study and then will be destroyed by shredding.

{Include the following statement.}

The data from the study may be published; however, you will not be identified by name.

{The following statement should be included ONLY if information about abuse or danger to self or others is likely to be discovered.}

Your identity will remain confidential unless disclosure is required by law, such as mandatory reporting of child abuse, elder abuse, or immediate danger to self or others.

Certificate of Confidentiality:
{Use the following paragraphs ONLY if a Certificate of Confidentiality is being requested through the National Institutes of Health. A Certificate of Confidentiality places legal burdens on an investigator and is not issued lightly. Most studies do not need a Certificate of Confidentiality. Further information may be obtained from the Certificates of Confidentiality Kiosk at http://grants1.nih.gov/grants/policy/coc/index.htm.}

To further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the investigators may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, the investigators continue to have ethical and legal obligations to report child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information private would immediately put you or someone else in danger, the investigators would release information to protect you or another person.

Financial costs to the participant:
{Include this section ONLY if participants are involved in ongoing care other than research activities.}

Funds are not available to cover the costs of any ongoing medical care and you remain responsible for the cost of non-research related care. Tests, procedures or other costs incurred solely for the purposes of research will not be your financial responsibility. If you have questions about your medical bill relative to research participation, you may contact (Name of principal investigator) at (Phone number) or (University faculty member's name if principal investigator is a student), at (Phone number).

Compensation in case of injury:
{Only include this section if the study involves greater than minimal risk to the participants. For research involving more than minimal risk, this statement should be included exactly as written. There must be at least two contact people; three if the principal investigator is a student.}

In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. (Put either The University of Cincinnati or the name of the sponsor) will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses. No other compensation is available. IF YOU BELIEVE YOU HAVE BEEN INJURED AS A RESULT OF RESEARCH, YOU SHOULD CONTACT (Name of principal investigator) at (Phone number), or (University faculty member's name if principal investigator is a student), at (Phone number) or the Chair of the Institutional Review Board – Social and Behavioral Sciences, at 513-558-5784.

Payments to participants:
{Describe financial reimbursement or recruitment incentive payment/gift for the participant, if applicable. If participants are to be PAID OR REIMBURSED for TRAVEL EXPENSES, specify dollar amount and payment schedule or other forms of reimbursement. Explain if the payment will be PRORATED if the participant withdraws or if the study is terminated by the investigator and according to what schedule.}

You will receive _____ for your participation in this study according to the following schedule: _____

Right to refuse or withdraw:
{Provide a statement explaining that participation is voluntary and that refusal to participate or withdrawal from the study at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled.}

Your participation is voluntary and you may refuse to participate, or may discontinue participation AT ANY TIME, without penalty or loss of benefits to which you are otherwise entitled. The investigator has the right to withdraw you from the study AT ANY TIME. Your withdrawal from the study may be for reasons related solely to you (for example, not following study-related directions from the investigator, etc.) or because the entire study has been terminated.

Offer to answer questions:
{Provide an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights. There must be at least two contact people; three if the principal investigator is a student.}

If you have any other questions about this study, you may call (Name of principal investigator) at (Phone number) or (University faculty member's name if principal investigator is a student), at (Phone number). If you

have any questions about your rights as a research participant, you may call the Chair of the Institutional Review Board – Social and Behavioral Sciences, at 513-558-5784.

LEGAL RIGHTS:

{Use common sense: if all participants must be competent adults who can read, the Legal Representative/Parent line, check box and witness line will not be needed. Additional instructions concerning signatures and disposition of consent documents are given at the end of this sample consent.}

Nothing in this consent form waives any legal right you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

I HAVE READ THE INFORMATION PROVIDED ABOVE. I VOLUNTARILY AGREE TO PARTICIPATE IN THIS STUDY. I WILL RECEIVE A COPY OF THIS CONSENT FORM FOR MY INFORMATION.

_____ _____

Participant Signature Date

_____ _____

Legal Representative/Parent Signature Date

☐ If verbal assent/consent was obtained, check this box and have a witness sign and date below.

_____ _____

Witness Signature (required only for verbal assent) Date

_____ _____

Signature and Title of Person Obtaining Consent Date

_____

Identification of Role in the Study

{version date}

{The consent statement should be signed by the adult participant (or, if the participant is blind, illiterate, certified incompetent, or a minor, it should be signed by his/her legal representative) and the study team representative. The IRB may determine and inform the principal investigator that the verbal assent of the participant is required when the participant's legal representative is signing the consent. If obtained, verbal assent must be documented on the consent. This may be done by checking the verbal assent box to indicate that verbal assent was obtained, or by the participant's signature; e.g., when older children are participants. <u>If the verbal assent box is checked, the signature of a witness is required.</u> The witness' signature signifies that all elements of the consent form were understood by the participant.}

{The signed consent document should be placed in the investigator's study file. The participant or the person signing for the participant must be given a copy of the consent form for their information (which may be unsigned).}

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL & BEHAVIORAL SCIENCES
CONSENT FORM CHECKLIST (to be used by reviewers)

PI / IRB # _____ Reviewer _____

The items checked below are either missing from the informed consent form or inappropriately stated. These items must be revised in order for the protocol to be approved by the IRB-S.

__ Heading needs to include university/college/departmental affiliation and principal investigator's name and phone number. (The heading should not include reference to the Institutional Review Board.)

__ Introductory statement (may be paraphrased, depending on the participants' reading and comprehension level).

> Before agreeing to participate in this study, it is important that the following explanation of the proposed procedures be read and understood. It describes the purpose, procedures, risks, and benefits of the study. It also describes the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made as to the results of the study.

__ Statement describing the purpose(s) of the study, and an indication of how many participants will be involved in the study.

__ Statement describing the expected duration of the participants' involvement in the study.

__ Description of procedures of the study, including identification of any procedures that are experimental.

__ Statement describing foreseeable risks or discomforts and benefits to the participant.

__ Statement describing appropriate alternative procedures or courses of treatment, if applicable, that might be advantageous to the participant. (Some of these may be educational interventions in the classroom, behavioral, social, etc.).

__ Statement describing the extent to which confidentiality of records identifying the participant will be maintained, security of data, and disposition of data at conclusion of the study.

__ For research involving MORE THAN MINIMAL RISK - Compensation in case of injury statement must be included. There must be at least two contact people; three if the PI is a student.

> "In the event that you become ill or injured from participating in this research study, emergency medical care will be provided to you. (Put either The University of Cincinnati or the name of the sponsor) will decide on a case by case basis whether to reimburse you for your out of pocket health care expenses. No other compensation is available. IF YOU BELIEVE YOU HAVE BEEN INJURED AS A RESULT OF RESEARCH, YOU SHOULD CONTACT (Name of principal investigator) at (Phone number), or (University faculty member's name if principal investigator is a student), at (Phone number) or the Chair of the Institutional Review Board – Social and Behavioral Sciences at 513-558-5784."

__ Statement describing financial costs and/or remuneration for the participant, if applicable.

__ Statement that participation is voluntary and that refusal to participate or withdrawal from the study at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled.

__ Explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and if applicable, who to contact in the event of a research-related injury (There must be at least two contact people; three if the PI is a student. See Compensation above.)

__ Conflicts of interest of the PI and key personnel of the research team must be disclosed in the consent.

__ Appropriate signature lines (participant, legal representative/parent, witness, study team)

__ Font size, layout, readability grade level is appropriate for participant's comprehension.

__Document needs to be proofread for typos and grammatical errors.

__Statement that participant will be given a copy of the consent for future reference (unless waived by the IRB-S).

Rev. 12/04

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
INVESTIGATOR RESPONSIBILITIES

1. The investigator is responsible for insuring that all research involving human subjects is submitted to and approved by the UC IRB-S prior to the initiation of the research.

2. The investigator who intends to involve human subjects in research will not make the final determination of exemption from applicable federal regulations or provisions. The investigator must submit a request for exemption that will be reviewed by the designated representative of the IRB-S.

3. The investigator is responsible for complying with all IRB-S policies, decisions, conditions, and requirements. The investigator is responsible for insuring that the research is implemented as specified in the approved protocol.

4. Unless otherwise authorized by the IRB-S, the investigator is responsible for obtaining and documenting informed consent, parental permission and/or child assent in accord with federal regulations (45CFR46 and 21CFR50).

5. The investigator is responsible for providing a copy of the approved IRB-S informed consent document to each participant, unless the IRB-S has specifically waived this requirement.

6. The investigator is responsible for promptly submitting to the IRB-S a request for modification of a previously approved protocol when:
   a) it is proposed to involve human participants and the activity previously had only indefinite plans for involvement of human participants.
   b) it is proposed to change the previously approved research activities. The changes cannot be initiated without IRB-S review and approval, except where necessary to eliminate apparent immediate risks to the participants.

7. The investigator must promptly report to the IRB-S and to the sponsoring federal agency (if appropriate) adverse events or other unanticipated problems involving risks to participants and others, in accordance with IRB-S policies and requirements.

8. The investigator is responsible for retention of signed consent documents for at least three years past completion of the research activity.

9. The investigator is responsible for reporting progress of approved research to the IRB-S, as often as and in the manner prescribed by the IRB-S on the basis of risks to participants, but at least once a year.

   NOTE: IRB-S approval expires as stated in the approval notification letter. Should the project extend beyond the expiration date, the investigator is responsible for submitting a Progress Report form to the IRB indicating that the project is continuing and summarizing the research activity to date. No research data may be collected without a current approval of the protocol, thus the investigator must allow sufficient time for the request for renewal to be reviewed and approved before expiration of the current approval. The investigator may print a Progress Report form from the IRB website.

10. The investigator is responsible for notifying the IRB-S when the research project is completed or terminated. The investigator may print a Progress Report form from the IRB website for this purpose. The IRB-S considers a research project to be complete if final conclusions have been made relating the collected data to the stated purpose of the protocol, whether or not the conclusions have been published.

11. The ethical obligations of the investigator do not end with the completion of data collection but continue as long as the data are analyzed, reported and maintained.

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
PROGRESS REPORT

CONTINUING APPROVAL OF RESEARCH

IRB-S review and approval of a project involving human subjects extends for not more than one year. The exact interval of approval and date of expiration are provided in the approval notification letter.

IRB-S approval of a project may specify the manner in which sensitive data should be handled. While all data should be handled in a confidential manner, special attention should be given to data with inherently linked identifiers (such as handwritten essays, videotapes, audiotapes, and similar identifiable information). The investigator must handle such data with care, employing the highest professional standards of ethical conduct. The investigator is responsible for continuing attention to matters of participant confidentiality, safeguarding of records, and proper and safe storage of data gathered throughout the life of the project and for three years after the study has been completed or terminated.

If the collection of data for a project extends past the approved time period, the project must be reviewed and reapproved by the IRB-S. The investigator must submit a Progress Report form to the IRB-S indicating that the project is continuing and summarizing protocol activity to date. A blank Progress Report form is provided below. No research data may be collected without a current approval of the protocol, thus the investigators must allow sufficient time for the request for renewal to be reviewed and approved before expiration of the current approval.

Federal regulations require that IRB review be carried out before a previously approved project may continue into another year. IF A PROGRESS REPORT HAS NOT BEEN APPROVED BY THE IRB-S BEFORE THE APPROVAL EXPIRATION DATE, FEDERAL REGULATIONS REQUIRE TERMINATION OF THE PROTOCOL.

MODIFICATION OF RESEARCH

Initial IRB-S approval extends only to procedures and data collection as specified in the originally approved study. If the investigator wishes to change the approved procedures, collect new kinds of data, or use the data for a purpose other than originally approved, IRB-S review of the proposed change is required. Any change to an approved research project must be reviewed and approved by the IRB-S before it may be implemented except where necessary to eliminate apparent immediate risks to the participants.

FINAL PROGRESS REPORT

When a project is completed or terminated a final Progress Report must be submitted. The IRB-S considers a research project to be complete if final conclusions have been made relating the collected data to the stated purpose of the protocol, whether or not the conclusions have been published. If the project is closed before the approval expiration date, the investigator may submit the final Progress Report early. (For example, if the study is being done as part of a graduate degree program and is completed in April, the final Progress Report may be submitted then, before the student graduates and leaves the University, even if the expiration date is not until October.) A blank Progress Report form is provided below.

The ethical obligations of the investigator, however, do not end with the completion of data collection, but continue as long as the data are analyzed, reported, and maintained.

10/03

Institutional Review Board - Social/Behavioral Sciences
University of Cincinnati
PO Box 670567
Cincinnati, OH 45267-0567

G-08 Wherry Hall
(513) 558-5784 Phone
(513) 558-4111 Fax

INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
PROGRESS REPORT

PI Name: _____ Address: _____ Email: hallbe@email.uc.
Faculty Advisor (if PI is a student): _____ ML _____ Email: _____
IRB# _____ **Title**: _____
_____

Please return this form to Claudia Norman at the UC IRB-S office address shown above. (A fax copy is acceptable.)
Original approval date: _____ Latest approval date: _____ Approval expiration date: _____

1. **STATUS:** This protocol is (check one category)
   - ☐ Active, continuing to enroll participants or obtain new data
   - ☐ Temporarily inactive
     a. When do you expect to reactivate the project? _____
     b. Why is it currently inactive? _____
   - ☐ Following established participants or analysis of existing data only, no new enrollment or new data obtained
   - ☐ Completed
   - ☐ Terminated (never started, or closed prematurely before data collection was complete) Explain briefly why project was terminated.

(NOTE: Modification of your study must be submitted **separately** from this Progress Report. Provide a description of the changes you want to make either by email or hard-copy. Attach a revised protocol and consent, if applicable. Identify **new language in bold** and ~~deleted language in strikethrough~~. Do NOT use color to show changes. **Changes must be approved by the IRB-S before they may be implemented** except where necessary to eliminate apparent immediate risks to the participants.)

2. **ENROLLMENT:** Number of participants enrolled since "Latest approval date" shown above _____

3. **CONSENT(S):** If this study includes signed consent/permission/assent, attach a copy of the first of each one signed after the "Latest approval date" shown above, with the participant's name and signature masked but the date of signature visible (e.g., if the study includes a Teacher Consent, Administrator Consent, Parent Permission and Child Assent, the first of each should be attached).

4. **FINDINGS:** Attach a summary of preliminary data analysis. Attach a summary of any new findings that may affect the willingness of participants to continue in this study and explain how participants will be notified of such findings.

5. Report on a separate page any untoward effects, unanticipated problems involving risks and/or complaints about the research that have occurred since the last approval date. If no problems have occurred please indicate: NONE _____

I certify that the information on this form is accurate to the best of my knowledge.

_____

PI or Faculty Advisor Signature **Date**

The information provided on this form will be reviewed by the IRB-S. Written notification of the Board's determination regarding continuation of this study will be provided to the PI and Faculty Advisor. 10/03

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD - SOCIAL AND BEHAVIORAL SCIENCES
RESOURCES

UC IRB-S Information:

IRB web address

www.med.uc.edu/irb

IRB-S meeting schedule (attached after "Definitions" below)
Deadlines for proposals to be submitted to the IRB-S
IRB-S meeting dates

IRB-S form packet
Link to IRB-S form packet
(approximately 28 pages, including all documents below)

Individual forms

1. General Information
2. Research Review Submission Form
   (with Appendix A: Conflict of Interest Form)
3. Protocol Format Checklist
   (including a list of items to be submitted)
4. Informed Consent Instructions
   (with sample Informed Consent Statement)
5. Informed Consent Checklist (used by reviewers)
6. Investigator Responsibilities
7. Progress Report for continuing approval or closure of protocol
   (with blank Progress Report form)
8. Resources

Resources:

1. American Psychological Association. (1982). Ethical Principles in the Conduct of Research with Human Participants. Washington, DC: American Psychological Association.
2. American Psychological Association. (1992). Ethical Principles of Psychologists and Code of Conduct. American Psychologist, 47, 1597-1611.
3. Sieber, J. E. (1992). *Planning ethically responsible research: A guide for students and internal review boards* (Applied Social Research Methods Series Vol. 31). Newbury Park, CA: SAGE Publications.
4. Ethical Principles and Guidelines for Research Involving Human Subjects (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm)
5. University of Cincinnati Training Site: www.researchtraining.uc.edu .
6. Office for Human Research Protection: Training Module for Assurances: http://ohrp.osophs.dhhs.gov/educmat.htm
7. National Institutes of Health: Human Participant Protection Education for Research Team: (http://cme.nci.nih.gov/).
8. Certificates of Confidentiality Kiosk: (http://grants1.nih.gov/grants/policy/coc/index.htm).

Definitions:
The University must adhere to federal regulations contained in Title 45 Code of Federal Regulations Part 46 (45CFR46). Two important definitions in these regulations involve “research” and “human subjects”.
(http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm - 46.103)

"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." 45CFR46.102(d)

NOTE: the “rule of thumb” used by IRB-S is: if it will be published or presented outside UC, it needs to be submitted for review.

"Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or
(2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are preformed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." 45CFR46.102(f)

NOTE: in some cases this includes data sets undergoing secondary analysis.

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES
2005-2006 MEETING SCHEDULE

(submission deadlines are for studies requiring Full-Board review)

Submissions during the academic year (September – May)

1. IRB-S encourages you to submit as soon as your application is ready. IRB-S review begins as soon as a submission is received.
2. If the IRB-S determines that your study meets federal criteria for Expedited review, then review will be independent of IRB-S meeting dates and deadlines shown below. Your submission will be sent to one or more IRB-S members for review. Their comments and questions will be sent to you by email and your responses forwarded back to them. When all their questions have been resolved, you will be notified of IRB-S approval by email, followed by hard-copy approval on letterhead.
3. If the IRB-S determines that your study requires Full-Board review, you will be notified by email and asked to attend the meeting to facilitate discussion. The following deadlines apply for those submissions that require Full-Board reviews.

IRB Meeting Date	**Deadline for Submissions**
October 20, 2005	September 30, 2005
November 17, 2005	October 28, 2005
December 8, 2005	November 18, 2005
January 19, 2006	January 4, 2006
February 16, 2006	January 27, 2006
March 16, 2006	February 24, 2006
April 20, 2006	March 31, 2006
May 18, 2006	April 28, 2006

Submissions during the summer (June – August)

1. Submit as soon as your proposal is ready. IRB-S review begins as soon as a submission is received.
2. If the IRB-S determines that your study meets federal criteria for Expedited, the process given above in #2 applies.
3. If the IRB-S determines that your study requires Full-Board review, arrangements will be made to convene a special meeting. You will be notified by email and asked to attend the meeting to facilitate discussion. The meeting will be scheduled at least two weeks after your protocol was received to allow time for IRB-S members to review your submission.